I. STATUS OF CLAIMS AND FORMAL MATTERS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

With entry of this amendment, claims 1-14 would still be pending in this application. Claim 1 has been amended to expedite prosecution which is discussed in further detail in section III. below (applicants reserve the right to pursue the scope of the originally filed claims in a continuation application). Claim 14 has been amended to address the rejection under 35 U.S.C. 112, second paragraph. No new matter has been added by these amendments.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112.

II. THE 35 U.S.C 112, 2nd PARAGRAPH REJECTIONS HAS BEEN OVERCOME

Claim 14 was rejected for allegedly lacking antecedent basis for the phrase "cellulose ether"). Although the applicants are unclear about the nature of this rejection, in order to advance prosecution, the applicants have added the phrase ---and the cellulose ether--- as it is a redundancy which does not change the scope of the claim.

III. THE 35 U.S.C 103(a) REJECTION HAS BEEN OVERCOME

Claims 1-14 were rejected as allegedly being obvious Rupprecht et al. (US 2002-0142036 -"Rupprecht") in view of Levin (US 6,432,986 -"Levin"). The applicants note that a Notice of Panel Decision from Pre-Appeal Brief Review form was mailed to the applicants wherein the box for "Proceed to Board of Patent Appeal and Interferences" was checked, but no explanation was given as to what was the "at least one actual issue" which still needed to be decided for Appeal or why the applicants arguments for the Pre-Appeal Brief Review were unpersuasive. As such, the applicants responses filed on 29 September 2009, 28 August 2009 and 15 April 2009 are believed to be still relevant here.

However, in order to expedite prosecution, the applicants have amended claim 1 to indicate that the active ingredient-containing layer has a concentration gradient from about 8%

by weight to about 50% by weight of lidocaine (this claim amendment is supported, e.g., by page 4, last two lines to page 5, first line and Example 4 in the specification).

As can be seen from Example 4 of the present application, one embodiment of the invention is to prepare a dosage form having an active-ingredient containing layer with a concentration gradient such as the one claimed in amended claim 1.

The lidocaine released from this embodiment of the claimed invention is depicted in Figure 1. It can bee seen from Figure 1 that the release of lidocaine and therefore, the action of lidocaine, can be extended to at least ***five hours*** of anesthetic/analgesic effect which is a surprising and unexpected result in view of the combined teachings of Rupprecht and Levin.

In contrast, e.g., Levin is directed toward intranasal administration and refers to lidocaine exhibiting a duration of action shorter than about one hour when intranasally administered (see col. 11, lines 26-28 of Levin). Levin's methods do nothing which improve upon the state of the art with respect to extending the time period of providing an anesthetic or analgesic effect.

At best, Levin merely discovered that "anesthesia of a dorsonasal nerve structure (DnNS) in a human patient experiencing a CNvD (cerebral neurovascular disorder) inhibits the CNvD or a symptom of the CNvD if the anesthesia persists for a period of at least about an hour, and preferably for a period of at least about two hours." The combination of Rupprecht and Levin does not suggest that bioadhesive pharmaceutical dosage forms such as those claimed by the applicants could be made to extend the anesthetic/analgesic effect far beyond what had previously been known in the art for intranasal administration.

Although the applicants believe that the claimed invention was previously in condition for allowance, with the amendment to the claims and the corresponding support for unexpected results, the preponderance of the evidence clearly shows that the applicants' clained bioadhesive pharmaceutical dosage form is unobvious over Rupprecht in view of Levin.

IV. CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/

Marilyn M. Brogan Howard C. Lee
Reg. No. 31,223 Reg. No. 48,104
Telephone: (212) 588-0800
Facsimile: (212) 588-0500